CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION

DEVICE ACTION PLAN

The Center for Biologics Evaluation and Research (CBER) regulates medical devices related to licensed blood and cellular products by applying appropriate medical device laws and regulations. The medical devices regulated by CBER are intimately associated with the blood collection and processing procedures as well as the cellular therapies regulated by CBER. CBER has developed specific expertise in blood, blood products and cellular therapies and the integral association of certain medical devices with those biological products supports the regulation of those devices by CBER.

During Fiscal Year 1998, CBER received eight Pre-Market Applications (PMA) applications/supplements and thirty-four 510(k) submissions. It completed reviews of four PMA applications/supplements and sixty-one 510(k) submissions. In addition to these medical device submissions, CBER also receives and reviews blood donor screening tests for licensure under section 351 of the Public Health Service Act.

Recently the FDA Modernization Act of 1997 enacted several significant changes in the regulation of medical devices. In addition, the Center for Devices and Radiological Health (CDRH) has embarked on reengineering initiatives to streamline the regulatory process for medical devices. During recent 406(b) Stakeholders public meetings, certain concerns have been stated by industry representatives regarding CBER's commitment to implement the FDAMA law and to consistently apply CDRH policy and procedures to the regulation of medical devices at CBER. Commenters also expressed an interest in CBER's improving its medical device review performance and its communication with industry.

The Center has developed a Device Action Plan in order to facilitate the implementation of the device provisions of FDAMA and to assure consistency of policy and procedures between CBER and CDRH. It will assess any differences that may exist and determine if those differences are justified in the interests of public health. This plan addresses areas of cooperation, coordination and communication between CBER and CDRH to assure harmonized activities. It focuses on Center review practices and performance goals under a managed review process. The plan also includes ongoing outreach activities to maintain input and feedback from industry and the public.

The attached Device Action Plan lays out general principles, and will require further development by CBER and CDRH to work out specific details. Close cooperation among the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health and the Office of Regulatory Affairs will be necessary for implementation.

Kathryn C. Zoon, Ph.D.
Director, Center for Biologics
Evaluation and Research

Elizabeth D. Jacobson, Ph.D.
Acting Director, Center for Devices
and Radiological Health

Dennis E. Baker
Associate Commissioner for
Regulatory Affairs

Jane E. Henney, M.D.
Commissioner of Food and Drugs

DATE: April 26, 1999